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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/994,458 | 11/26/2001 | Ken K. Tseung | LABV / 04 | 9498 |

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 09/994,458 | Applicant(s) TSEUNG ET AL | |
| | Examiner Maureen M. Wallenhorst | Art Unit 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-19, 26-28 and 38-49 is/are pending in the application.
- 4a) Of the above claim(s) 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19, 26-28 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. In response to the request for the withdrawal of the finality of the last Office action mailed on February 10, 2005 and the supplemental after final amendment, both received on May 6, 2005, prosecution in the instant application is being re-opened in order to institute a new grounds of rejection.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 15, 18-19, 26-28 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalra et al (US Patent no. 5,948,359, submitted in the Information Disclosure Statement filed on March 28, 2002) in view of Levine et al (US Patent no. 5,854,075, submitted in the IDS filed on November 12, 2003) and Wolf et al (US Patent no. 4,793,491).

Kalra et al teach of a method and apparatus for the automated staining of tissue specimens on slides. The apparatus comprises a supporting framework 20 to which a moveable arm 30 in three dimensions is attached. Motors for moving the arm 30 are provided under the control of a computer or other electronic control system that allows programming of the movement of the arm between various different work locations on or within the framework. A hollow tip head is located on the arm 30 so that liquids or gases can be dispensed or withdrawn through the head. The apparatus also comprises a holder area in the framework 20 for holding a plurality of reagent containers, each containing a staining reagent, and a holder area or tray for holding a plurality of microscopic slides. See Figure 1 in Kalra et al. The slides having tissue specimens thereon are placed horizontally in a tray on the framework 20. The apparatus is programmed for the individual slides to be treated with staining reagents according to a staining protocol. In one embodiment of the apparatus and method, a bar-code technology is used where a data storage label is affixed at a predetermined location on the reagent containers. The bar codes can store various types of information thereon such as the name of the reagent solution, the manufacture date, the expiration date, the serial number and the reagent volume. In addition, there is a pre-printed label applied to the upper surfaces of the slides. The content of these bar codes includes the protocol to be used in processing a particular slide. Before initiating an operation, the apparatus moves an optical reader device such as a laser bar-code scanner around

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the bar codes located on both the microscopic slides and reagent vials. The control system will recognize the reagents and slides to be treated, and will calculate the required volumes of reagents. The movable arm 30 is moved to different locations over the framework 20 by the action of various motors that operate in combination with sliding tracks to position the arm 30 at its desired location within the framework 20. An X-axis track 32, a Y-axis track and a Z-head 70 move the arm 30. See Figure 9 in Kalra et al. The laser bar code scanner 410 is located on the right side of the Z head 70 so that the bar code scanner moves with the hollow tip head that withdraws and dispenses reagents from the reagent containers. The scanner 410 on the movable arm 30 moves vertically and horizontally to read the bar codes on the slides and reagent containers row-by-row and column-by-column. The apparatus reads the bar codes associated with both the reagent vials and slides, and thereafter, the control system determines the parameters needed to carry out a particular staining protocol for a particular slide. See lines 46-55 in column 4, lines 38-66 in column 5, lines 1-25 in column 8, lines 31-49 in column 9, lines 14-32 in column 12, lines 46-67 in column 16, lines 1-20 in column 17 and lines 24-33 in column 18 of Kalra et al. Kalra et al fail to teach that the bar codes on the reagent vials and slides are two-dimensional data storage elements such as two-dimensional bar codes, and fail to teach that the reaction vials have the specific structure of an upper and lower base wall connected by side walls and a nadir in the base wall aligned with an opening in the upper wall.

Levine et al teach of an automatic blood film preparation apparatus that comprises a plurality of test tubes or other receptacles that contain specimens from which a blood smear is to be made. Located on the test tubes or receptacles are bar codes that identify the samples. Levine et al teach that the bar codes can be two-dimensional bar codes that are known in the art. Levine

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et al disclose that the advantages of using two-dimensional bar codes is the elimination of the need for interfacing with a laboratory computer, and the increased amount of information that can be stored on the test tubes. See lines 666-67 in column 9 and lines 1-5 in column 10 of Levine et al.

Based upon the combination of Kalra et al and Levine et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the bar codes on the reagent vials and slides taught in the automatic staining device of Kalra et al as two-dimensional bar codes since Levine et al disclose that conventional two-dimensional bar codes provide an increased amount of information and eliminate the need for interfacing with a laboratory computer.

Wolf et al teach of a shipping vessel for storing and transporting fluid chemicals. The vessel assembly 1 comprises an inner fluid container 20 having an upper wall and an opposing lower wall spaced apart from one another along an imaginary line passing through the upper and lower walls. The upper wall contains an opening therein, and the lower wall contains a slight concave well 42 as a nadir that is aligned with the opening of the upper wall. The well 42 accommodates a tubular ducting 24 of a fluid delivery insert assembly. Wolf et al teach that an advantageous feature of the concave well 42 is that it allows for a maximum of 99.5% by volume of the fluid chemical contents to be delivered from the vessel under normal pressurized delivery. The concave well 42 allows virtually all of the liquid volume of the chemical in the container to be dispensed without any wastage in the bottom of the container. See Figure 2 and lines 39-56 in column 3 of Wolf et al.

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Based upon the combination of Kalra et al and Wolf et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the reagent vials used in the staining apparatus taught by Kalra et al with the structure of the chemical vessel taught by Wolf et al so as to provide an easily accessible liquid reagent to a probe inserted into a reaction vial even when only a small volume of reagent is left in the vial, since Wolf et al teach that the nadir or low point 42 in the vessel provides a means for collecting any remaining liquid reagent therein in a more accessible location to a probe inserted into the vessel and allows virtually all of the liquid volume of the chemical in the vessel to be dispensed without any wastage in the bottom of the vessel.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalra et al in view of Levine et al and Wolf et al as applied to claims 15, 18-19, 26-28 and 38-40 above, and further in view of Tseung et al (US Patent no. 6,746,851). For a teaching of Kalra et al, Levine et al and Wolf et al, see previous paragraphs in this Office action. Kalra et al fail to teach that the control system of the automatic staining apparatus has a stat function for adding stat slides to the tray for staining.

Tseung et al teach of an automatic staining apparatus for staining tissue specimens on slides that comprises a tray holding a plurality of slides, a rack holding a plurality of reagent containers, a robotic delivery system including a movable probe for withdrawing reagents from the containers and depositing them on the slides, and a control system programmable for conducting particular staining protocols by controlling the movement of the robotic delivery system. The reagent containers and slides have bar codes thereon that identify the slide preparation protocol to be performed. The autostainer includes a stat function that allows a user

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to add new slides of high priority to the apparatus for staining. A user presses a stat button on the control system, and the autostainer then commences operation by scanning the bar codes on the stat slides to determine the staining protocols to be performed on those slides. These stat slides are given priority for staining over the other slides in the apparatus. See lines 35-48 in column 5 and lines 23-30 in column 6 of Tseung et al.

Based upon the combination of Kalra et al, Levine et al and Tseung et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the control system in the automatic staining apparatus taught by Kalra et al with a stat function for adding stat slides to the tray for staining, similar to the stat function taught by Tseung et al, since Tseung et al disclose that a stat function in an automatic staining apparatus allows a user to pause the operation of the device to load additional slides that need immediate testing and analysis, and then restart the apparatus so that the stat slides of high priority are stained first before any of the remaining slides in the apparatus are stained.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalra et al in view of Levine et al and Wolf et al as applied to claims 15, 18-19, 26-28 and 38-40 above, and further in view of Rhett et al (US Patent no. 5,839,091, submitted in the IDS filed on March 28, 2002). For a teaching of Kalra et al, Levine et al and Wolf et al, see previous paragraphs in this Office action. Kalra et al fail to teach that the control system of the automatic staining apparatus has a touchscreen display in electrical communication with the control system for both displaying and inputting information to the control system.

Rhett et al teach of an automatic staining apparatus for staining tissue specimens on slides that comprises a tray holding a plurality of slides, a rack holding a plurality of reagent containers,

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a robotic delivery system including a movable probe for withdrawing reagents from the containers and depositing them on the slides, and a control system 190 programmable for conducting particular staining protocols by controlling the movement of the robotic delivery system. See Figure 1b in Rhett et al. The control system 190 includes a touchscreen display in the form of a computer screen depicted in Figure 1a of Rhett et al. The touchscreen display allows a user to input information such as a user name and password (see Figure 6), as well as displays a set of functions that a user can select from such as programming the autostainer for a run, initializing the autostainer, cleaning the autostainer, displaying help information, etc. See Figure 7 in Rhett et al.

Based upon the combination of Kalra et al, Levine et al and Rhett et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the control system of the automatic staining apparatus taught by Kalra et al with a touchscreen display in electrical communication with the control system since Rhett et al teach that a touchscreen display in connection with a control system of an autostainer allows a user to interact with the apparatus by choosing selected protocols and functions to run in the apparatus, and allows a user to receive results immediately in a viewable form.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

May 16, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1800~~ 1700